

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOHN TOMSON, derivatively on behalf of
OHR PHARMACEUTICAL, INC.,

Plaintiff,

v.

MICHAEL FERGUSON, JASON S. SLAKTER,
SAM BACKENROTH, ORIN HIRSCHMAN,
IRACH TARAPOREWALA, THOMAS M.
RIEDHAMMER, and JUNE S. ALMENOFF,

Defendants,

and

OHR PHARMACEUTICAL, INC.,
Nominal Defendant.

Case No. _____

**STOCKHOLDER DERIVATIVE
COMPLAINT**

JURY TRIAL DEMANDED

VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

Plaintiff John Tomson (“Plaintiff”), by and through his attorneys, alleges, upon information and belief based upon, *inter alia*, the investigation made by and through his attorneys, which included, among other things, a review of news articles, press releases, public filings made by Ohr Pharmaceuticals, Inc. (“Ohr” or the “Company”) with the U.S. Securities and Exchange Commission (the “SEC”), and other publicly available information, except as to those allegations that pertain to Plaintiff himself, which are alleged upon knowledge, as follows:

1. This is a stockholder derivative action brought for the benefit of nominal defendant Ohr against certain of its officers and members of its Board of Directors (the “Board”) seeking to remedy Defendants’ breaches of fiduciary duties, corporate waste and unjust enrichment that began at least as early as April 2014. Defendants’ actions resulted in millions of dollars in damages

to Ohr's reputation, goodwill, and standing in the business community, and have exposed the Company to millions of dollars in potential liability for violations of state and federal laws.

2. Ohr is a clinical stage pharmaceutical company developing novel therapies for ophthalmic diseases. In 2009, Ohr purchased the rights to Squalamine lactate ("Squalamine" and "OHR-102"), a compound derived from the liver of a dogfish shark, from Genaera Corporation ("Genaera"). Prior to selling Squalamine to Ohr, Genaera had attempted to develop the compound into a treatment for Wet Age-Related Macular Degeneration ("Wet AMD"), which is an eye disorder that damages the center of the retina, causing vision loss. Genaera conducted clinical trials involving patients with Wet AMD and Squalamine, but stop testing the drug in 2007 because the tests had disappointing results. In particular, Genaera's trials showed that there was no attractive or pragmatic option for the registration and commercialization of Squalamine for the treatment of Wet AMD.

3. After purchasing Squalamine, Ohr repackaged it into an eye-drop (it was previously administered intravenously) and began testing it with patients with Wet AMD. In 2012, Ohr launched a phase II clinical trial of Squalamine in patients with Wet AMD, OHR-002 or the "IMPACT Trial."¹ The IMPACT Trial was designed to enroll 142 patients in two arms: a treatment arm and a control (placebo) arm.² In the treatment arm, patients received Squalamine eye drops twice a day in combination with injections of Lucentis (the "Squalamine Arm") as needed. In the control arm, patients

¹ To secure approval by the Food and Drug Administration ("FDA"), a new drug must typically succeed in three phases of clinical trials. Phase I trials are usually the first trials to be conducted on people and are designed to determine the highest dosing amount for the drug that is safe and does not cause serious side effects. If the phase I trial shows that the drug is safe, phase II trials are conducted in several hundred patients to determine whether the drug is effective and how long the effect lasts in patients. If the drug is shown to be effective in the phase II trials, then phase III trials are conducted in a broader number of patients to further demonstrate whether the drug offers a treatment benefit to patients and whether the drug is safe for the target population.

² A "treatment arm" refers to the group of patients in a clinical trial that receives the new treatment. A "control arm" refers to the group of patients in a clinical trial who do not receive the new treatment in order to compare the treatment to receiving no treatment or the standard of care.

received placebo eye drops twice a day in combination with injections of Lucentis (the “Lucentis Monotherapy Arm”). The primary endpoint of the trial was the mean number of Lucentis rescue injections required for patients to maintain vision over the course of nine months and the secondary endpoint was whether patients had improvement in vision as measured by the Early Treatment Diabetic Retinopathy Study eye scale (the “Standard Eye Chart”).

4. Lucentis, or ranibizumab, was the first therapy to treat Wet AMD approved by the FDA. Lucentis is the current standard of care for Wet AMD patients and is administered through intravitreal injections into the eye every 4 to 8 weeks, as the drug’s efficacy degrades over time.

5. Before any results from the IMPACT Trial were announced, Ohr launched a promotional campaign for Squalamine. In presentations and SEC filings, Ohr and Defendants misleadingly represented that the prior phase II trials conducted by Genaera for Squalamine were successful, stating that “the administration of Squalamine produced beneficial effects and significant improvement in best corrected visual acuity[.]” However, Ohr and Defendants did not disclose that Genaera had ceased testing Squalamine after determining that results from these trials were weak. Nor did the Company or Defendants disclose that the visual acuity results for the Genaera trials of Squalamine were actually worse than the results from the trials used to gain the FDA approval of Lucentis. After using these misleading statements to drive up Ohr’s stock price, Ohr initiated the first of its four stock offerings on April 8, 2014, raising approximately \$18 million.

6. The Company’s and Defendants’ misleading statements did not end there. On June 24, 2014, Ohr announced the interim results for the IMPACT Trial (the “Interim Results”). Ohr reported that patients in the Squalamine Arm had a mean vision improvement of 10.4 letters on the Standard Eye Chart while the patients in the Lucentis Monotherapy Arm had a mean improvement of 6.3 letters, a relative difference of 4.1 letters. Ohr and Defendants hyped these results, proclaiming that

the visual acuity numbers were the “most clinically relevant measure” for determining Squalamine’s efficacy in treating Wet AMD.

7. Ohr and Defendants continued touting the Interim Results throughout 2014, calling the results “truly remarkable” and claiming that they showed a “robust and rapid response.” Ohr also assured investors that the trial’s control arm—the Lucentis Monotherapy Arm—had not underperformed as prior studies involving Lucentis, stating that “the visual acuity gains for the Lucentis Monotherapy Arm were consistent with those observed in previous clinical studies using Lucentis [.]”

8. Ohr’s and Defendants’ statements concerning the Interim Results were false and misleading. In the prior trials of Lucentis, patients gained a mean of 7.94 letters or 1.64 letters higher than the Lucentis Monotherapy Arm’s Interim Results. If patients in the Lucentis Monotherapy Arm of the Interim Results had performed in line with Lucentis’s prior trials, the difference in visual acuity between the Squalamine Arm and Lucentis Monotherapy Arm would have been 2.46 letters, which is not a clinically meaningful difference. As a member of Ohr’s Scientific Advisory Board explained, a Wet AMD treatment must improve vision by at least 4 letters to be considered clinically meaningful. Rather than truthfully disclose and explain this shortcoming in the Interim Results, Ohr conducted a second offering of common stock on February 6, 2015, raising approximately \$25 million.

9. Thereafter, on March 27, 2015, Ohr announced the final visual acuity results for 70 patients in the IMPACT Trial who had “classic-containing” Wet AMD lesions (the “Classic Lesions Results”), which are lesions that have a demarcated border. As announced by the Company, the patients in the Squalamine Arm showed a mean improvement in visual acuity of 10.5 letters and the Lucentis Monotherapy Arm showed a mean improvement in visual acuity of 5.4 letters, a difference of 5.1 letters.

10. Just as before, the Company touted these results as “clinically meaningful” and showing “a clear efficacy signal.” However, once again, the Company and Defendants did not disclose that the Lucentis Monotherapy Arm materially underperformed in the IMPACT Trial compared to the results from past Lucentis trials—thereby lowering the benchmark against which the Squalamine Arm was being compared, and creating a misleading impression of the Squalamine Arm’s performance. Had the Lucentis Monotherapy Arm performed consistently with past Lucentis trials and achieved a visual acuity gain of 7.94 letters, the difference between the Squalamine Arm and the Lucentis Monotherapy Arm shrinks from would have only been 2.56 letters, a difference which is not clinically meaningful.

11. On May 11, 2015, Ohr announced the final results for patients with occult Wet AMD lesions smaller than 10 mm in size (the “Occult Lesions Results”). Occult Wet AMD lesions are lesions that have a diffuse, poorly-defined border. As announced, the results showed that the mean visual acuity for patients in the Squalamine Arm improved by 11 letters and the mean visual acuity for patients in the Lucentis Monotherapy Arm improved by 5.7 letters, a difference of 5.3 letters. Again, Defendants failed to disclose that, had the Lucentis Monotherapy Arm not materially underperformed in comparison to its historical trials, the results would not have been clinically meaningful. Had patients in the Lucentis Monotherapy Arm performed consistently with prior Lucentis trials and achieved a gain of 7.94 letters, the relative difference between the two arms would be only 3.06 letters.

12. Continuing to push Squalamine, on March 29, 2016, Ohr announced that the Company was initiating a phase III trial for Squalamine in patients with Wet AMD (the “MAKO Trial”). The MAKO Trial was designed to have two arms like the IMPACT Trial, but was to enroll 650 patients and span two years. Riding high on the enthusiasm the Defendants generated for the

MAKO Trial, the Company conducted a third offering of common stock, raising approximately \$6.9 million.

13. On April 5, 2017, Ohr announced yet another offering—its fourth—raising approximately \$12.7 million in proceeds. In total, Ohr raised \$62 million in its four offerings.

14. The truth about Squalamine finally emerged in January 2018. Before the market opened on January 5, 2018, before the market opened, Ohr announced the MAKO Trial's results. The results were a disaster. Patients in the Squalamine Arm of the MAKO Trial performed worse than those in the Lucentis Monotherapy Arm of the MAKO Trial, achieving a mean gain of 8.33 letters versus a mean gain of 10.58 letters. On this news, the Company's common stock price plummeted \$1.64, or approximately 81%, from \$2.02 per share on January 4, 2018, to \$0.38 per share on January 5, 2018.

15. As alleged herein, throughout the Relevant Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose, *inter alia*, that:

- a) Genaera's prior clinical trials of Squalamine did not demonstrate that it improved visual acuity outcomes;
- b) Genaera terminated its development of Squalamine for the treatment of Wet AMD because Genaera concluded, based on the data available from its trials, that Squalamine was unlikely to produce vision improvement with the speed or frequency necessary to compete with Lucentis;
- c) The 6.3-letter mean visual acuity gain observed in the Lucentis Monotherapy Arm of the Interim Results underperformed the mean 7.94-letter-gain observed in prior studies of Lucentis;
- d) Had the Lucentis Monotherapy Arm of the Interim Results performed as well as in prior studies of Lucentis, the improvement of the Squalamine Arm compared to the Lucentis Monotherapy Arm would not have been clinically meaningful;
- e) The visual acuity gains observed in the Lucentis Monotherapy Arms of the Classic Lesions Results and the Occult Lesions Results underperformed prior Lucentis studies;

- f) Had the Lucentis Monotherapy Arms of the Classic Lesions Results and the Occult Lesions Results performed as well as in prior studies of Lucentis, the improvement of the Squalamine Arms compared to the Lucentis Monotherapy Arms would not have been clinically meaningful;
- g) As a result of the foregoing, Defendants' statements about Ohr's business, operations, and prospects, were false and misleading and/or lacked a reasonable basis; and
- h) The Company failed to maintain adequate disclosure controls and procedures with respect to its drug candidates, particularly Squalamine.

16. Defendants' misfeasance and omissions have severely damaged this once valuable franchise. Moreover, Defendants' wrongful acts have caused the Company to face a complicated and expensive-to-defend securities class action. Accordingly, Defendants' violations of the law have severely damaged Ohr.

17. Nevertheless, the Ohr Board has not taken any legal action against the directors and officers responsible for this debacle. Nor will it, because each of the Defendants is interested in the outcome of any such legal action. By this action, Plaintiff seeks to vindicate Ohr's interests against its wayward fiduciaries.

STATEMENT OF JURISDICTION AND VENUE

18. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) in that Plaintiff and Defendants are citizens of different states and the matter in controversy exceeds \$75,000.00, exclusive of interests and costs. Plaintiff is a citizen of Pennsylvania and no Defendant is a citizen of Pennsylvania.

19. This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have. Venue is proper in this district because Defendant Ohr is headquartered in this District and because a substantial portion of the wrongs complained of herein occurred in this District.

PARTIES

20. Plaintiff is a current stockholder of nominal defendant Ohr and has continually held shares since January 2014. Plaintiff was, therefore, a stockholder at the time of the wrongdoing alleged herein. Plaintiff is a citizen of Pennsylvania.

21. Nominal Defendant Ohr is incorporated under the laws of the State of Delaware and maintains its principal executive offices at 800 Third Ave, 11th Floor, New York, NY 10022. The Company's stock is listed on the NASDAQ under the ticker symbol "OHRP." As of May 15, 2018, Ohr had 56,466,428 shares of common stock outstanding. OHR is a citizen of New York and Delaware.

22. Defendant Michael Ferguson ("Ferguson") is a director and has been the Chairman of the Board since May 2017. Ferguson knowingly, recklessly, or with gross negligence: (1) caused or allowed Ohr to disseminate improper statements concerning Ohr's lead product Squalamine; (2) caused or allowed Ohr to disseminate improper statements concerning its business, operations, and prospects; and (3) failed to maintain adequate internal controls and disclosure procedures with respect to Ohr's drug candidates. In 2017, Ferguson received 500,000 stock options. Ferguson is a citizen of Maryland.

23. Defendant Jason S. Slakter ("Slakter") has been a director of Ohr since January 2015 and Ohr's Chief Executive Officer ("CEO") since August 7, 2015. Slakter knowingly, recklessly, or with gross negligence: (1) caused or allowed Ohr to disseminate improper statements concerning Ohr's lead product Squalamine; (2) caused or allowed Ohr to disseminate improper statements concerning its business, operations, and prospects; and (3) failed to maintain adequate internal controls and disclosure procedures with respect to Ohr's drug candidates. Slakter received \$610,622 and \$1,958,813 in 2015 and 2016, respectively, and 390,000 stock options in 2017, in

executive compensation and other compensation from Ohr not justified by the Company's performance while under his stewardship. Slakter is a citizen of New York.

24. Defendant Sam Backenroth ("Backenroth") has been Ohr's Chief Financial Officer since April 12, 2010. Backenroth knowingly, recklessly, or with gross negligence: (1) caused or allowed Ohr to disseminate improper statements concerning Ohr's lead product Squalamine; (2) caused or allowed Ohr to disseminate improper statements concerning its business, operations, and prospects; and (3) failed to maintain adequate internal controls and disclosure procedures with respect to Ohr's drug candidates. In 2014, 2015, and 2016, Backenroth received \$1,176,426, \$664,623, and \$911,720, respectively, in executive compensation and other compensation from Ohr not justified by the Company's performance while under his stewardship. In 2017, Backenroth received 350,000 stock options. Backenroth is a citizen of New York.

25. Defendant Orin Hirschman ("Hirschman") has been a director of Ohr since March 2009. He has been a member of the Audit Committee since 2015. Hirschman knowingly, recklessly, or with gross negligence: (1) caused or allowed Ohr to disseminate improper statements concerning Ohr's lead product Squalamine; (2) caused or allowed Ohr to disseminate improper statements concerning its business, operations, and prospects; and (3) failed to maintain adequate internal controls and disclosure procedures with respect to Ohr's drug candidates. In 2015 and 2016, Hirschman received \$425,445 and \$211,678, respectively, in executive compensation and other compensation from Ohr not justified by the Company's performance while under his stewardship. In 2017, Hirschman received 245,000 stock options. Hirschman is a citizen of Maryland.

26. Defendant Irach Taraporewala ("Taraporewala") served as the Company's CEO between April 12, 2010, and August 7, 2015, and as the Company's Chief Technology Officer

from August 7, 2015, and December 11, 2015. Taraporewala also served as the Company's President and a directors, resigning both positions on December 11, 2015. Taraporewala knowingly, recklessly, or with gross negligence: (1) caused or allowed Ohr to disseminate improper statements concerning Ohr's lead product Squalamine; (2) caused or allowed Ohr to disseminate improper statements concerning its business, operations, and prospects; and (3) failed to maintain adequate internal controls and disclosure procedures with respect to Ohr's drug candidates. In 2014 and 2015, Taraporewala received \$1,196,230 and \$799,683, respectively, in executive compensation and other compensation from Ohr not justified by the Company's performance while under his stewardship. Taraporewala is a citizen of New York.

27. Defendant Thomas M. Riedhammer ("Riedhammer") has been a director of Ohr since April 2013. Riedhammer is a Chairman of the Audit and Compensation Committees. He has served as Chairman of the Audit Committee since at least 2014. Riedhammer knowingly, recklessly, or with gross negligence: (1) caused or allowed Ohr to disseminate improper statements concerning Ohr's lead product Squalamine; (2) caused or allowed Ohr to disseminate improper statements concerning its business, operations, and prospects; and (3) failed to maintain adequate internal controls and disclosure procedures with respect to Ohr's drug candidates. In 2015 and 2016, Riedhammer received \$425,445 and \$211,678, respectively, in executive compensation and other compensation from Ohr not justified by the Company's performance while under his stewardship. In 2017, Riedhammer received 170,000 stock options. Riedhammer is a citizen of Florida.

28. Defendant June S. Almenoff ("Almenoff") has been a director of Ohr since May 2013. Almenoff is a member of the Audit and Compensation Committees, and has served as a member of the Audit Committee since at least 2014. Almenoff knowingly, recklessly, or with gross

negligence: (1) caused or allowed Ohr to disseminate improper statements concerning Ohr's lead product Squalamine; (2) caused or allowed Ohr to disseminate improper statements concerning its business, operations, and prospects; and (3) failed to maintain adequate internal controls and disclosure procedures with respect to Ohr's drug candidates. In 2015 and 2016, Almenoff received \$425,445 and \$211,678, respectively, in executive compensation and other compensation from Ohr not justified by the Company's performance while under his stewardship. In 2017, Almenoff received 170,000 stock options. Almenoff is a citizen of North Carolina.

29. The Defendants identified in paragraphs 22 through 28 are collectively referred to herein as the "Defendants."

THE FIDUCIARY DUTIES OF OHR'S OFFICERS AND DIRECTORS

30. Each officer and director of Ohr owed the Company and its shareholders the duty to exercise a high degree of care, loyalty, and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of complained of herein involves fraudulent misconduct by Ohr's directors and officers – a knowing, intentional, and culpable violation of the directors' and officers' obligations as directors and/or officers of Ohr, and the absence of good faith on their part concerning their duties to the Company and its shareholders. The officers' misconduct has been ratified by the board, which has failed to take any legal action on behalf of the Company against them.

31. By reason of their positions as officers, directors, and/or fiduciaries of Ohr and because of their ability to control the business and corporate affairs of Ohr, Defendants owe Ohr and its shareholders fiduciary obligations of good faith, loyalty, and candor, and were and are required to use their utmost ability to control and manage Ohr in a fair, just, honest, and equitable manner. Defendants were and are required to act in furtherance of the best interests of Ohr and its

shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to Ohr and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

32. Defendants, because of their positions of control and authority as directors and/or officers of Ohr, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Ohr, each Defendant had knowledge of material non-public information about the financial condition, operations, and future business prospects of Ohr.

33. To discharge their duties, the officers and directors of Ohr were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Ohr were required to, among other things:

- a) Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;
- b) Exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner, and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the investing public;
- c) Properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's financial results; and
- d) When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.
- e) Exercise its clawback authority to clawback compensation from the directors and officers responsible for the above improprieties.

34. As members of the Board's Audit Committee, Hirschman, Riedhammer, and Almenoff were required to comply with the Charter of the Audit Committee. The Charter confirms that each director serving on the Audit Committee is responsible for maintaining appropriate accounting and internal control systems, discussing matters related to the Company's financial statements, reviewing and investigating matters pertaining to the integrity of management or adherence to the standards of business conduct, and for discussing earnings press releases and financial presentations with management.

35. Specifically, the Audit Committee Charter provides:

PURPOSE

The purposes of the Audit Committee are:

- (1) to oversee the accounting and financial reporting policies and practices and the internal controls of the Company;
- (2) to oversee the quality and objectivity of financial statements and the independent audit thereof; and
- (3) to act as a liaison between the independent auditors and the full Board of Directors.

* * *

RESPONSIBILITIES

A. The function of the Audit Committee is oversight. Management's responsibility is to maintain appropriate systems for accounting and internal control; and the auditors' responsibility is to plan and carry out a proper audit. The Audit Committee is vested with the following powers and responsibilities:

- (1) to evaluate the performance of the independent auditors and recommend the selection, retention, or termination of auditors;
- (2) to ensure that the auditors submit a formal written statement delineating all relationships between the auditors and the Company, consistent with Independence Standards Board Standard 1, such written statement to be submitted to the Audit Committee on a periodic basis;
- (3) to evaluate the independence of the auditors; to receive the auditors' specific representation as to their independence, to otherwise engage in a dialogue with the auditors with respect to any disclosed relationships or services that may impact the objectivity and independence of the

auditors; and to make recommendations to the Board of Directors based on such evaluations;

- (4) to meet with the independent auditors, including private meetings, as necessary:
 - (a) to review the arrangements for and scope of the annual audit and any special audits;
 - (b) to discuss any matters of concern relating to the financial statements, including any adjustments to such statements recommended by the auditors;
 - (c) to consider the auditors' comments with respect to the financial policies, procedures and internal accounting controls of the Company and management's responses thereto;
 - (d) to discuss with the auditors the matters required to be discussed by Statement on Accounting Standards No. 61 as modified or supplemented; and
 - (e) to review the form of opinion the auditors propose to render to the Board of Directors and stockholders;
- (5) to review with management and the independent auditors the annual audited financial statements of the Company in the Form 10-K and the Company's quarterly financial statements in the Form 10-Q, including the Company's specific disclosures under "Management's Discussion and Analysis of Financial Condition and results of Operations" and any other matters required to be reviewed under applicable legal, regulatory or Nasdaq requirements, in each case prior to its filing;
- (6) to consider the effect upon the Company of any changes in accounting principles or practices proposed by management or the auditors;
- (7) to obtain and review at least annually a formal written report from the independent auditor delineating: the auditing firm's internal quality-control procedures; the auditing firm's independence; and any material issues raised within the preceding five years by the auditing firm's internal quality-control reviews, by peer reviews of the firm, or by any governmental or other inquiry or investigation relating to any audit conducted by the firm; to review steps taken by the auditing firm to address any findings in any of the foregoing reviews; and in order to assess auditor independence, to review at least annually all relationships between the independent auditor and the Company;
- (8) to set policies for the hiring of employees or former employees of the Company's independent auditor;
- (9) to determine appropriate funding for (a) compensation to the auditors for audit and non-audit services, (b) compensation to any advisors employed by the Audit Committee, and (c) ordinary administrative

expenses of the Audit Committee that are necessary or appropriate in carrying out its duties;

- (10) **to review and investigate any matters pertaining to the integrity of management or adherence to standards of business conduct as required in the policies of the Company**, including (a) regular reviews of the compliance processes and programs in general and the corporate ombudsman process in particular and (b) meeting, as deemed appropriate, with the general counsel and other Company officers or employees;³
- (11) **to discuss with management and the independent auditor, as appropriate, prior to their release to the public, earnings press releases and financial presentations provided to analysts and rating agencies;**
- (12) as required by Nasdaq listing standards, to discuss with management the Company's risk assessment and risk management practices and the guidelines, policies and processes for risk assessment and risk management;
- (13) to oversee the Company's risk policies and processes relating to financial statements, financial systems, financial reporting processes, compliance and auditing, and allowances for losses, as well as the guidelines, policies and processes for monitoring and mitigating such risks;
- (14) to establish procedures for (a) receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and (b) the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters; and
- (15) to report its activities to the full Board of Directors on a regular basis **and to make such recommendations with respect to the above matters and other matters as the Audit Committee may deem necessary or appropriate**, including the preparation of the report required by the rules of the Securities and Exchange Commission to be included in the Company's annual proxy statement.

Emphasis added.

36. As the Company's CEO, Slakter is required to comply with the Company's Code of Ethics for Senior Executive and Financial Officers. The Code confirms that Slakter was responsible for maintaining appropriate accounting and internal control systems, discussing

³ All emphases are added to quotations and all internal citations and internal quotations are omitted unless otherwise noted.

matters related to the Company's financial statements, reviewing and investigating matters pertaining to the integrity of management or adherence to the standards of business conduct, and for discussing earnings press releases and financial presentations with management.

37. Specifically, the Code provides:

Purpose of Code of Ethics.

The purpose of this Code of Ethics is to promote the honest and ethical conduct of our Senior Executive and Financial Officers (described below), including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; to promote full, fair, accurate, timely and understandable disclosure in periodic reports required to be filed by Ohr Pharmaceutical, Inc. (the "Company"); and to promote compliance with all applicable rules and regulations that apply to the Company and its officers.

* * *

Accurate Periodic Reports and Other Public Communications

As you are aware, full, fair, accurate, timely and understandable disclosure in our periodic reports filed with the SEC and in our other public communications is required by SEC rules and is essential to our continued success. Please exercise the highest standard of care in preparing such materials. We have established the following guidelines in order to ensure the quality of our periodic reports.

All Company accounting records, as well as reports produced from those records, must be kept and presented in accordance with the laws of each applicable jurisdiction.

All records must fairly and accurately reflect the transactions or occurrences to which they relate. All records must fairly and accurately reflect in reasonable detail the Company's assets, liabilities, revenues and expenses.

The Company's accounting records must not contain any false or intentionally misleading entries.

No transaction may be intentionally misclassified as to accounts, departments or accounting periods or in any other manner.

All transactions must be supported by accurate documentation in reasonable detail and recorded in the proper account and in the proper accounting period.

No information may be concealed from the internal auditors or the independent auditors.

Compliance with Generally Accepted Accounting Principles and the Company's system of internal accounting controls is required at all times.

Compliance with Law and this Code of Ethics

You are expected to comply with both the letter and spirit of all applicable governmental rules and regulations and this Code of Ethics, and to report any suspected violations of applicable governmental rules and regulations or this Code of Ethics to the Chief Financial Officer or the Chief Executive Officer. No one will be subject to retaliation because of a good faith report of a suspected violation. If you fail to comply with this Code of Ethics or any applicable laws or regulations, you may be subject to disciplinary measures, up to and including discharge.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

38. In committing the wrongful acts complained of herein, Defendants pursued, joined in, or participated in the pursuit of a common course of conduct and acted in concert with one another in furtherance of a common plan or design. In addition to the wrongful conduct complained of herein giving rise to primary liability, Defendants also aided and abetted and/or assisted each other in breach of their fiduciary duties.

39. Each of the defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such action to substantially assist the commission of the wrongdoing complained of herein, each defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of the wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

SUBSTANTIVE ALLEGATIONS

I. Wet AMD

40. Wet macular degeneration is a chronic eye disease that causes blurred vision or a blind spot in a person's visual field. See Mayo Clinic, Wet macular degeneration, <https://www.mayoclinic.org/diseases-conditions/wet-macular-degeneration/symptoms-causes/syc-20351107> (last visited Aug. 21, 2018). It is generally caused by abnormal blood vessels

that leak fluid or blood into the macula, which is the part of the retina responsible for central vision.

Id.

41. Wet macular degeneration is one of two types of age-related macular degeneration, representing about 10% of all age-related macular degeneration cases. *Id.* The other type is called dry macular degeneration and is the more common type of macular degeneration. *Id.* It is also less severe. *Id.*

42. The cause of Wet AMD is currently unknown. *Id.* It develops in people who have had dry macular degeneration and occurs when abnormal blood vessels, known as choroidal neovascularization (“CNV”) grow under the retina and macula. *See* The American Macular Degeneration Foundation, Wet Macular Degeneration, <https://www.macular.org/wet-amd> (last visited Aug. 21, 2018). These new blood vessels may then bleed and leak fluid, causing the macula to bulge or lift up from its normally flat position, thus distorting or destroying central vision. *Id.* Areas of abnormal blood vessels and altered tissue are referred to as “lesions.” A patient with wet AMD may have his or her vision affected as shown below:

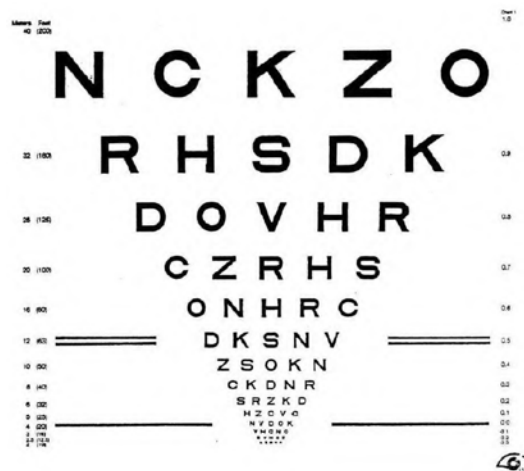


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Mayo Clinic, Wet macular degeneration.

43. When a patient has Wet AMD, a lesion appears on the surface area on the retina where the CNV has occurred. *See Ursula Schmidt-Erfurth, Three-Dimensional Angiography of Classic and Occult Lesion Types in Choroidal Neovascularization*, 48 Investigative Ophthalmology & Vision Science 1751 (April 2007). There are two types of lesions: classic and occult. *Id.* Classic lesions have a demarcated border, are more aggressive, and cause early and substantial vision loss. *Id.* Occult lesions have a diffuse, poorly defined border and often present with long-term maintenance of vision until the retina becomes damaged. *Id.*

44. Visual acuity is the clearness or sharpness of vision measured at a distance of 20 feet. *See American Optometric Association, Visual Acuity: What is 20/20 Vision?*, <http://www.aoa.org/patients-and-public/eye-and-vision-problems/glossary-of-eye-and-vision-conditions/visual-acuity?sso=y> (last visited Aug, 21 2018). The Standard Eye Chart is characterized by lines of five letters each decreasing in size, which is used to measure visual acuity. *See Jerry Isaacson, Ohr Pharmaceutical, Inc. Initiation Report*, LifeSci Capital, 11 (July 28, 2015). Below is an example of the Standard Eye Chart:



45. In Wet AMD clinical trials, patients would read from an eye chart before and after treatment is applied to determine whether visual acuity has increased, stabilized, or decreased following the treatment.

II. Prior Squalamine Trials Were Failures

46. Prior to Ohr's acquisition of Squalamine, it was being developed and analyzed by Genaera. Genaera began developing Squalamine for the treatment of Wet AMD in 2001 and gave the product the trade name "EVIZON." Wet AMD is a disease affecting the cells in the macula, which is an area that forms the center of the retina and is the region of the eye responsible for central vision. Patients with Wet AMD suffer debilitating vision loss and it is the leading cause of blindness.

47. Between 2003 and 2007, Genaera hosted numerous clinical trials of Squalamine patients with Wet AMD. "Study 209" was a phase II clinical trial designed to assess the safety of two doses of Squalamine (40 mg and 20 mg) and its potential effect on visual acuity over a two-year period. In Study 209, intravenous treatment of Squalamine was administered weekly for the first four weeks and monthly after that. Interim data of 108 subjects after the first six months showed lackluster results. In the 40 mg group, a mere 5% of subjects gained vision (defined as a gain of 15 letters or more in visual acuity) and 79% of subjects maintained vision (which is officially defined as a loss of less than 15 letters in visual acuity). In the 20 mg group, only 4% of subjects gained vision and 69% maintained vision. In the control group, none of the subjects gained vision and 71% maintained vision. Genaera never disclosed the final data from this study.

48. Following the conclusion of Study 209, Genaera soon began enrolling patients into another phase II clinical trial concerning Squalamine, "Study 212." This study was designed to evaluate whether higher doses of Squalamine would produce stronger results. However, it quickly became apparent that any more testing of Squalamine in Study 212 would be a waste given the disappointing results of Study 209. Genaera subsequently announced that it was terminating its Squalamine (known during that time as EVIZON) clinical program, stating:

[P]reliminary information from investigators on patients enrolled to date in Study 212 suggests that EVIZON is unlikely to produce vision improvement with the speed or frequency necessary to compete with recently introduced treatments. Faced with this discouraging information, as well as evolving FDA guidance on clinical endpoints, we have concluded that there is no attractive or pragmatic option for the registration and commercialization of EVIZON for the treatment of wet AMD. As a result, we cannot justify continuing to expend our limited resources on the clinical development of EVIZON.

49. Around this time, development of Lucentis as a treatment for Wet AMD continued. On June 20, 2006, the FDA approved Lucentis as the first treatment for Wet AMD. Unlike Squalamine, which was still only being tested in small-scale phase II studies, FDA approval of Lucentis was based on data from two large phase III clinical trials—MARINA and ANCHOR. The visual acuity results from these trials were far superior to the Study 209 results. In the Lucentis studies, 40% of patients treated with Lucentis improved vision (defined as the gain of 15 letters or more in visual acuity) at one year and 95% of patients maintained vision (defined as the loss of less than 15 letters in visual acuity) at one year. Compared to Genaera’s Study 209, where only 5% of subjects improved vision and 79% maintained vision, Lucentis performed eight times better than Squalamine.

III. Ohr Acquires Squalamine

50. In June 2009, Genaera filed for bankruptcy and began liquidating its assets. Ohr entered into an Asset Purchase Agreement with the Genaera Liquidating Trust to purchase the rights to Squalamine and another pharmaceutical compound, paying \$200,000 for both compounds. As outlined in the Asset Purchase Agreement, Ohr acquired all “trade secrets, know-how . . . , processes and techniques, and research and development information, ideas, [and] technical data” for Squalamine and Genaera’s “records of the development of Squalamine and related analog compounds . . . including lab notebooks, FDA filings and correspondence, research reports, research and clinical data, manufacturing and production records, and patent correspondence.”

51. On April 12, 2010, Ohr announced that Irach Taraporewala was replacing Andrew Limpert as CEO, making this Taraporewala's fourth new position in only five years. That very same day, Backenroth was named CFO. Only 26 years old and a recent college graduate, Backenroth had zero management experience and very little hands-on financial experience, as he had only worked in investment banking for two years at Benchmark Company, LLC prior to joining Ohr. Neither Taraporewala nor Backenroth had a medical degree. Despite that issue, they remained the only two officers on Ohr's management team until 2014.

52. In order to bring attention to Squalamine, the Board caused Ohr hired stock-pumper, Corporate Profile LLC ("Corporate Profile"). Corporate Profile was a "broadcasting website where fashion meets finance" in which "New York's top on-air talent" pumps select stocks. It produced slick videos made to look like official news stories but which were actually promotional pieces. These videos touted Ohr as a "hot stock pick" and claimed that Squalamine had the potential to create a monumental shift in the way patients are treated for Wet-AMD.

53. On June 21, 2011, Ohr announced that it had repackaged Squalamine for from an intravenous infusion to a topical eye drop. Remarkably, without having tested the solution in animals or humans, Dr. Hirschman boldly stated that the "Squalamine eye drop program has the potential to create a monumental shift in the way patients are treated for Wet-AMD[.]" Unlike Lucentis, which required frequent eye injections, Taraporewala noted that this was a "very patient-friendly method of treatment."

54. In September 2012, Ohr initiated its first Squalamine phase II trial, OHR-002 (the "IMPACT Trial"). The study was a phase II clinical trial to evaluate the efficacy and safety of Squalamine for the treatment of Wet AMD by comparing Squalamine in combination with Lucentis to Lucentis alone. It was a randomized, double-blind, placebo-controlled study that

enrolled 142 Wet AMD patients at 21 clinical sites in the U.S. At the start of the trial, each patient's visual acuity was measured to establish a vision baseline. Shortly after, the patients were divided into two arms: (1) the Squalamine Arm (*i.e.*, the treatment arm); and (2) the Lucentis Monotherapy Arm (*i.e.*, the placebo control arm). In the Squalamine Arm, patients received an initial dose of Lucentis and thereafter self-administered Squalamine eye drops twice daily with additional injections of Lucentis on an as needed basis *a/k/a pro re nata* ("PRN") for nine months. In the Lucentis Monotherapy Arm, patients received their first dose of Lucentis and then were asked to self-administer placebo eye drops twice daily with additional injections of Lucentis PRN for nine months.

55. The trial protocol included an initial analysis upon the completion of the treatment period in 50% of the patients. The primary endpoint measured in each arm was the mean number of Lucentis rescue injections required for patients to maintain vision over the course of nine months.⁴ The secondary endpoints included patients' best corrected visual acuity as measured by the number of letters a patient could read on the Standard Eye Chart and the number of adverse events observed as a measure of safety and tolerability.

IV. Ohr Begins Touting Squalamine

56. In 2013, Ohr needed cash and funding desperately. Ohr's annual report, filed in January of that year, disclosed that there is "substantial doubt about our ability to continue as a going concern." In fact, the Company reported no revenue and suffered losses of over \$5 million for the year. In order to raise the funding they needed, Defendants' caused Ohr to engage in a scheme to artificially inflate its stock price.

⁴ A primary endpoint is the main, pre-determined objective of the trial to establish the effectiveness and/or safety features of a drug to support approval of the drug by the FDA. Secondary endpoints may be selected to demonstrate additional effects or benefits of the drug.

57. The scheme began with the Company registering on the NASDAQ in June 2013. After, to raise its now NASDAQ-registered stock price, Ohr began a media blitz, presenting at seven separate conferences in seven months to end 2013. During these presentations, Ohr touted its prospects for Squalamine and claimed that it “may provide several potential advantages over the FDA approved current standards of care[,]” even though the IMPACT Trial was never designed to compare the efficacy of Squalamine and Lucentis.

58. Defendants’ plan proved successful as Ohr stock price rose from \$6.61 per share on October 21, 2013, to an all-time high of \$19.65 per share on March 14, 2014, raising its share price by almost 200%.

59. On April 8, 2014, Defendants decided to take advantage of Ohr’s pumped-up stock price and caused Ohr to initiate an offering of its common stock. With only \$3.4 million in cash on hand, Ohr entered into a subscription agreement for a direct offering of common stock in which the Company sold 1.8 million shares at \$10.00 per share, for gross proceeds of approximately \$18 million. In the offering documents, the Board caused Ohr to promote Squalamine by stating that it had already demonstrated “significant improvement in best corrected visual acuity” in previous phase II trials. Specifically, in Ohr’s Form 424B5 it filed with the SEC on April 8, 2014, the Company stated:

Using an intravenous formulation in over 250 patients in Phase I and Phase II trials for the treatment of Wet-AMD, the trials demonstrated that the molecule had biological effect and maintained and improved visual acuity outcomes, with both early and advanced lesions responding.

* * *

In Phase II clinical trials using the intravenous formulation of Squalamine, stabilization or improvement in visual activity was observed in the vast majority of patients, with both early and advanced lesions responding and few drug-related ocular or systemic effects observed. In a number of patients whose wet-AMD had progressed to an advanced stage, the administration of

Squalamine produced beneficial effects and significant improvement in best corrected visual acuity. As opposed to the approved current standard of care therapy, Squalamine does not require direct injection into the eye.

60. On April 29, 2014 and May 9, 2014, Ohr issued press releases with updates on its clinical trial program. The press releases stated in relevant part:

The drug, using an intravenous administration in over 250 patients in Phase I and Phase II trials for the treatment of wet-AMD, showed favorable biological effect and maintained and improved visual acuity outcomes.

61. On May 13, 2014, Ohr filed its quarterly financial report for the second quarter of 2014 with the SEC on Form 10-Q (“2Q 2014 10-Q”). The 2Q 2014 10-Q was signed by Taraporewala and Backenroth and contained the same misleading statements as in the Form 424B5 filed with the SEC on April 8, 2014.

62. Thereafter, the Board decided to strengthen its management team with members more experienced in ophthalmology, who could assist in its ongoing ophthalmology trial program. On May 15, 2014, Ohr announced that it had entered into an agreement to acquire the ophthalmology assets of SKS Ocular LLC (“SKS”). As part of the acquisition, SKS’s principals joined Ohr’s management team: Glenn L. Stoller (“Stoller”) joined as CSO; Slakter joined as Chief Medical Officer; and Peter Kaiser joined as Senior Vice President of Product Development. At that time, Ohr failed to mention that Stoller had previously served as a principal investigator on Genaera’s phase II trials of Squalamine or that Genaera had determined that Squalamine was unlikely to produce vision improvement with the speed or frequency necessary to compete with Lucentis.

V. Ohr Announces the Results of the Interim Results of the IMPACT Trial

63. On June 24, 2014, Ohr announced the Interim Results of its IMPACT Trial. The press release was also attached as exhibit 99.1 to the Form 8-K filed with the SEC that same day. The results showed that, for the visual acuity endpoint, the mean improvement in visual acuity for

the Squalamine Arm was 10.4 letters, whereas the mean improvement in visual acuity for the Lucentis Monotherapy Arm was 6.3 letters, a 4.1 letter difference between the two arms. The Company touted these results as “truly remarkable[,]” explaining that “[v]isual acuity is the most clinically relevant endpoint for back-of-the-eye disorders. For wet-AMD patients, such enhanced gains of visual acuity over standard-of-care anti-VEGF treatments, and the restoration of vision lost to this devastating disease . . . is a very important clinical outcome.”

64. In the press release, the Company and Slakter stated:

Ohr Pharmaceutical, Inc. (Nasdaq:OHRP), an ophthalmology research and development company, today announced positive top-line interim results for its double-masked, placebo-controlled Phase II clinical trial of Squalamine eye drops in patients with wet age-related macular degeneration (wet AMD). The data demonstrated a positive benefit in visual function across multiple clinically relevant endpoints, including a mean change in visual acuity at the end of study visit for the interim analysis group of +10.4 letters with Squalamine eye drops plus Lucentis® PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit (p=0.18). The visual acuity improvements were seen as early as four weeks and the relative difference in visual acuity between the two treatment arms continued to increase throughout the study.

* * *

The Squalamine-treated group demonstrated improved best-corrected visual acuity (BCVA) gains relative to the placebo group at all timepoints evaluated from four to 38 weeks. In the interim analysis group, 48.3 percent of Squalamine-treated patients showed BCVA gains of ≥ 15 letters (≥ 3 lines) on a standard ETDRS eye-chart, compared with 21.2 percent in the placebo arm at the end of the study (p=0.025). In addition, patients receiving Squalamine drops were more than twice as likely to gain ≥ 4 and ≥ 5 lines of vision compared with patients in the placebo eye drop arm (≥ 4 lines p=0.022, ≥ 5 lines p=0.059). Importantly, the visual acuity gains for the placebo eye drop arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment.

* * *

“The beneficial effects of Squalamine on visual acuity that we've seen thus far, through its inhibition of multiple angiogenic growth factors and pathways, and in particular, the improvement in gains of three or more lines in vision compared with the placebo group, are truly remarkable,” said Dr. Jason Slakter[.]

65. In the power point presentation accompanying the announcement, the Company further stated:

Conclusions

- **Squalamine eye drops combined with Lucentis PRN demonstrated marked improvements over the Lucentis PRN + placebo drops in:**
- **Mean gains in Visual Acuity (p=0.18)**
- **% of patients gaining >15 letters (p=0.025)**
- **% of patients with >4 and >5 line vision gain (p=0.022 and p=0.059)**

Summary

- **The interim results of the Squalamine eye drop program demonstrate dramatic vision gains across the full spectrum of exudative AMD compared to Lucentis + placebo drop regimen**

66. Despite touting the trial's results, the Company did not explain that the only reason that the Interim Results showed a difference of 4.1-letters in visual acuity between the Squalamine Arm and the Lucentis Monotherapy Arm was because the visual acuity results for the Lucentis Monotherapy Arm underperformed the historical results observed in previous studies of Lucentis, including the studies that served as the basis for the FDA's approval of Lucentis to treat Wet AMD. In fact, the data from other studies of Lucentis monotherapy showed that patients improved in average 7.94 letters from baseline. If the Lucentis Monotherapy Arm in the IMPACT Trial had not underperformed prior Lucentis studies and achieved a vision gain of 7.94 letters, the relative difference in vision improvement between the Squalamine Arm (10.4 letters) and the Lucentis Monotherapy Arm (6.3 letters) would shrink from 4.1 letters to 2.46 letters, a difference of 40%, which is not a clinically meaningful difference. The chart below lists the results from prior studies of Lucentis monotherapy in Wet AMD patients receiving the same dose of Lucentis as the patients in the IMPACT trial:

Study Name	Date of Publication	BCVA Improvement With Injections As Needed Per Set Protocol	BCVA Improvement With Monthly Injections
MARINA	2006	N/A	7.2 letters at 9 mos. 7.2 letters at 12 mos. 6.6 letters at 24 mos.
ANCHOR	2006	N/A	11.4 letters at 9 mos. 11.3 letters at 12 mos.
PrONTO	2007	9.3 letters at 12 mos. 11.1 letters at 24 mos.	N/A
A Treat and Extend Regimen Using Ranibizumab for Wet AMD: Clinical and Economic Impact	2010	9.7 letters at 24 mos.	N/A
Inject and Extend Dosing Versus Dosing as Needed	2011	2.3 letters at 12 mos. as needed 10.8 letters at 12 mos. inject & extend	N/A
CATT	2011	7.2 letters at 9 mos. 6.8 letters at 12 mos. 6.7 letters at 24 mos.	7.5 letters at 9 mos. 8.5 letters at 12 mos. 8.8 letters at 24 mos.
VIEW1	2012	N/A	8.1 letters at 12 mos.
VIEW2	2012	N/A	9.4 letters at 12 mos.
FUSION	2012	5.6 letters at 12 mos.	N/A
HARBOR	2013	8.2 letters at 12 mos. 7.9 letters at 24 mos.	10.1 letters in at 12 mos. 9.1 letters at 24 mos.
VIEW 96 Week Results	2013	7.9 letters at 22 mos.	N/A
IVAN	2013	7.2 letters at 12 mos. ⁵ 4.9 letters at 24 mos.	
LUCAS	2013	8.2 letters at 12 mos.	N/A
GEFAL	2013	3.63 letters at 12 mos.	N/A
MANTA	2013	4.1 letters at 12 mos.	N/A
Reducing the clinical burden of ranibizumab treatment for neovascular age-	Apr. 2014	9.8 letters at 12 mos.	N/A

⁵ The “as needed” and “monthly” results were reported together.

related macular degeneration using an individually planned regimen			
BRAMD	Apr. 2014	N/A	6.4 letters at 12 mos.

67. The term “clinically meaningful” is used to define whether or not a treatment provides a meaningful benefit on an aspect of how a patient feels, functions, or survives as a result of treatment. *See* Jessica J. Lee, MD, MMSc, *Defining Clinical Benefit in Clinical Trials: FDA Perspective*, FDA (2015). For a Wet AMD treatment to be clinically meaningful, the treatment must improve vision by at least 4 letters, according to Dr. David Boyer, a member of Ohr’s own Scientific Advisory Board.

68. The Company also did not explain that the Lucentis Monotherapy Arm materially underperformed in the Interim Results. Rather, the Company stated the opposite, assuring the market that “the visual acuity gains for the placebo eye drop arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment.”

69. Ohr then once again hired a stock pumper, Vista Partners LLC (“Vista”), to further tout the Interim Results. Just two days after the Interim Results were announced, Vista issued a press release and a “research report” purportedly raising its price target for Ohr from \$14 to \$31. At the time, Ohr’s stock was trading at \$7.31 per share. In its report, Vista lauded the Interim Results and made grandiose claims regarding Squalamine’s potential effect on the Wet AMD market. Vista also went on to say that “[t]he Company believes that showing [visual acuity] improvements is far more meaningful to a wet AMD patient than reducing the number of injections . . .” Vista’s press release and report never mentioned that it had been paid by Ohr to publish promotional materials. The report, referenced briefly in the press release, admitted in a small footnote on the last page though that:

This report has been prepared by Vista Partners LLC (“Vista”) with the assistance [sic] OHR Pharmaceutical, Inc. (“the Company”) based upon information provided by the Company. Vista has not independently verified such information, and in addition, Vista has been compensated by the Company for advisory services for a one year period.

70. Vista’s press release was quickly picked up and quoted by the media, and Ohr’s stock price soared 60% in two days, from a low of \$6.86 to a high of \$10.97. *See* Andrew Meola, *Why Ohr Pharmaceuticals (OHRP) Stock is Soaring Today*, TheStreet (June 26, 2014), <https://www.thestreet.com/story/12758833/1/why-ohr-pharmaceuticals-ohrp-stock-is-soaring-today.html> (last accessed Aug. 21, 2018); *see also* John Seward, *OHR Pharmaceutical Up 30%, Partly Recoups 2-Day Losing Streak* (June 26, 2014), <https://finance.yahoo.com/news/ohr-pharmaceutical-30-partly-recoups-184408448.html> (last accessed Aug. 21, 2018).

71. On August 13, 2014, Ohr issued a press release announcing that it had presented additional interim IMPACT trial results at the annual meeting of the American Society of Retinal Specialists. In the press release, the Company stated:

The data demonstrated a visual acuity and anatomical benefit for the group of patients receiving the combination of OHR-102 and Lucentis® PRN (“OHR-102 arm”) versus placebo eye drops plus Lucentis PRN (“Lucentis monotherapy arm”). . . .

The OHR-102 treated group demonstrated improved best-corrected visual acuity (BCVA) gains relative to the Lucentis monotherapy group at all timepoints evaluated from four to 38 weeks. In the interim analysis group, 48.3 percent of OHR-102 treated patients showed BCVA gains of ≥ 15 letters (≥ 3 lines) on a standard ETDRS eye-chart, compared with 21.2 percent in the monotherapy arm at the end of the study ($p=0.025$). In addition, patients receiving OHR-102 drops were more than twice as likely to gain ≥ 4 and ≥ 5 lines of vision compared with patients in the Lucentis monotherapy arm (≥ 4 lines $p=0.022$, ≥ 5 lines $p=0.059$). **Mean gain in visual acuity was +10.4 letters in the OHR-102 arm vs. +6.3 letters in the Lucentis monotherapy arm ($p=0.18$).**

Importantly, the visual acuity gains for the Lucentis monotherapy arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment.

72. On August 18, 2014, Ohr filed its quarterly financial report for the third quarter of 2014 with the SEC on Form 10-Q (“3Q 2014 10-Q”). The 3Q 2014 10-Q was signed by Taraporewala and Backenroth and stated:

The data demonstrated a positive benefit in clinically relevant visual function in the OHR-102 arm across multiple key secondary endpoints. . . . In the interim analysis group, 48.3 percent of OHR-102 treated patients showed best corrected visual acuity (“BCVA”) gains of ≥ 15 letters (≥ 3 lines) on a standard early treatment diabetic retinopathy study eye-chart, compared with 21.2 percent in the Lucentis monotherapy arm at the end of the study ($p=0.025$). In addition, patients receiving OHR-102 drops were more than twice as likely to gain ≥ 4 and ≥ 5 lines of vision compared with patients in the Lucentis monotherapy arm (≥ 4 lines $p=0.022$, ≥ 5 lines $p=0.059$). **Mean change in visual acuity at the end of study visit was +10.4 letters with OHR-102 eye drops plus Lucentis PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit ($p=0.18$).**

73. On December 22, 2014, Ohr issued a press release announcing its financial results for the year ended September 30, 2014. In the press release, the Company and Taraporewala stated:

“Treatment with OHR-102 demonstrated an improvement in visual acuity, the most clinically relevant endpoint for back-of-the-eye disorders. . . . The positive IMPACT data and successful outcome of our recent FDA meeting give us a clear path for future registration studies for OHR-102[.]” stated Dr. Irach Taraporewala[.]

The data demonstrated a positive benefit in clinically relevant visual function in the OHR-102 arm across multiple key secondary endpoints. . . . In the interim analysis group, 48.3 percent of OHR-102 treated patients showed best corrected visual acuity (BCVA) gains of ≥ 15 letters (≥ 3 lines) on a standard early treatment diabetic retinopathy study eye-chart, compared with 21.2 percent in the Lucentis monotherapy arm at the end of the study ($p=0.025$). Patients receiving OHR-102 drops were more than twice as likely to gain ≥ 4 and ≥ 5 lines of vision compared with patients in the Lucentis monotherapy arm (≥ 4 lines $p=0.022$, ≥ 5 lines $p=0.059$). **Mean change in visual acuity at the end of study visit was +10.4 letters with OHR-102 eye drops plus Lucentis PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit ($p=0.18$).**

74. That same day, the, Ohr filed its annual financial report for the year ended September 30, 2014 with the SEC on Form 10-K (the “2014 10-K”). It was signed by Taraporewala and Backenroth. In the report, the Company stated:

The data demonstrated a positive benefit in clinically relevant visual function in the OHR-102 arm across multiple key secondary endpoints. In the interim analysis group, 48.3 percent of OHR-102 treated patients showed best corrected visual acuity (“BCVA”) gains of ≥ 15 letters (≥ 3 lines) on a standard early treatment diabetic retinopathy study eye-chart, compared with 21.2 percent in the Lucentis monotherapy arm at the end of the study ($p=0.025$). . . . In addition, patients receiving OHR-102 drops were more than twice as likely to gain ≥ 4 and ≥ 5 lines of vision compared with patients in the Lucentis monotherapy arm (≥ 4 lines $p=0.022$, ≥ 5 lines $p=0.059$). **Mean change in visual acuity at the end of study was +10.4 letters with OHR-102 eye drops plus Lucentis PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit ($p=0.18$).**

75. Also, that same day the Company held a conference call to discuss the financial results for the year ended September 30, 2014. During the call, Slakter and the Company stated in relevant part:

The results of this interim analysis showed that Squalamine Eye Drops, in conjunction with Lucentis, provided substantial gains in visual acuity in this patient population, exceeding the visual acuity gains seen in the group receiving Lucentis alone. More specifically, this interim analysis data showed a mean gain in visual acuity of 10.4 letters with Squalamine Eye Drops plus Lucentis PRN, versus 6.3 letters in the placebo eye drop plus PRN Lucentis arm at the end of the nine-month study. This represents a 65% additional relative benefit in vision gain.

76. With the stock price heavily inflated due to the enthusiasm generated by Vista’s publications and Defendants’ false and misleading statements regarding the Interim Results, on February 6, 2015, Defendants caused Ohr to launch a second public offering of 3,703,704 shares of common stock at \$6.75 per share for gross proceeds of approximately \$25 million.

77. On February 5 and 6, 2015, Ohr filed a prospectus supplement with the SEC on Form 424B5 in connection with its offering. The prospectus contained the same false and misleading statements as the 2014 10-K.

78. On February 9, 2015, Ohr issued a press release announcing the financial results for its first quarter of 2015. The press release stated in relevant part:

Data showing topical administration of OHR-102 used in combination with Lucentis® demonstrated marked improvements over Lucentis monotherapy in multiple visual acuity parameters in the IMPACT study.

79. On February 9, 2015, Ohr filed its financial report for the first quarter of 2015 with the SEC on Form 10-Q (“1Q 2015 10-Q”). The 1Q 2015 10-Q was signed by Taraporewala and Backenroth and contained the same false and misleading statements as the 2014 10-K.

VI. Ohr Touts the IMPACT Trial’s Classic and Occult Lesions Results

80. Shortly thereafter, in its press release issued on March 27, 2015, Ohr touted the IMPACT Trial’s Classic Lesions Results. The Company stated that the final results for 70 patients with classic-containing lesions included mean gains in visual acuity of 10.5 letters in the Squalamine Arm and 5.4 letters in the Lucentis Monotherapy Arm, a relative difference of 5.1 letters between the two arms. In the press release, the Company stated:

Positive Visual Acuity Benefit in Classic Containing CNV Using OHR- 102 Combination Therapy . . .

In patients with classic CNV (ITT-LOCF), mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.1 letters.

81. The Company touted the visual acuity data for the Classic Lesions Results with Defendant Slakter stating during a conference call, stating that the 5.1 letter improvement in visual acuity in the Squalamine Arm “demonstrates a positive and clinically meaningful treatment effect of OHR-102 combination therapy in classic containing CNV.”

82. When touting these results, Defendants failed to tell the market that the Lucentis Monotherapy Arm of the Classic Lesions Results **materially underperformed** in the IMPACT Trial. In prior Lucentis studies, Lucentis monotherapy patients experienced an average **7.94 letter improvement** in visual acuity. Had patients in the Lucentis Monotherapy Arm of the Classic Lesions Results performed steadily with prior Lucentis studies and achieved vision gains of approximately 7.94 letters, the relative difference between the visual acuity gains for the Lucentis Monotherapy Arm (5.4 letters) and the Squalamine Arm (10.5 letters) for the Classic Lesions Results would not be clinically meaningful, as the difference would shrink from 5.1 letters to 2.56 letters, a decline of 50%.

83. On May 7, 2015, Ohr issued another press release touting the results of the Classic Lesions Results from the IMPACT trial, stating:

In the mITT population with lesions containing classic choroidal neovascularization (classic containing lesions) (OHR-102 n=37, Lucentis® monotherapy n=28), mean gains in visual acuity at month nine were +11 letters for the OHR-102 combination arm and +5 letters with Lucentis monotherapy, a clinically meaningful benefit of 6 letters. . . .

The results from the IMPACT study demonstrate that topically administered OHR-102 combination therapy can lead to improved visual function in patients with wet AMD and, importantly, that the efficacy results may be determined by lesion size and composition,” stated Dr. Jason Slakter, Chief Medical Officer at Ohr. **“There was a clear and clinically meaningful benefit in patients whose lesions contained some classic CNV.”**

84. On May 11, 2015, Ohr filed its financial report for the second quarter of 2015 with the SEC on Form 10-Q (“2Q 2015 10-Q”). The 2Q 2015 10-Q was signed by Taraporewala and Backenroth and stated in relevant part concerning the Classic Lesion Results:

Data from the IMPACT study demonstrated that, in that the intent-to-treat (ITT-LOCF) population with classic containing choroidal neovascularization (CNV) (OHR-102 n=38, Lucentis® monotherapy n=32), 42% of the patients receiving OHR-102 achieved a ≥ 3 line gain at nine months, as compared to 28% in the Lucentis monotherapy group. In patients with classic CNV (ITT-LOCF), **mean**

gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.1 letters.

85. Also on May 11, 2015, the Company held a conference call with respect to its second quarter results. During the call, the Company touted both the Classic Lesion Results and Occult Lesions Results from the IMPACT trial.

86. On July 13, 2015, Ohr issued a press release, announcing the “positive results” of OHR-102 for patients with central retinal vein occlusion. The press release also was attached as exhibit 99.1 to the Form 8-K filed with the SEC on July 15, 2015. The press release stated that:

“The positive results of this Phase II study demonstrates the role of OHR-102 combination therapy in RVO and represent an important milestone for the development of OHR-102 in the treatment of this disease,” said Dr. Jason Slakter, Chief Medical Officer of Ohr. “This trial constitutes the second clinical study in a retinal vascular disorder which has shown a positive and clinically meaningful benefit in visual acuity using OHR-102 combination therapy versus an intravitreal anti-VEGF injection alone. The consistency of the efficacy data in this study, combined with the favorable safety profile of OHR-102, we believe warrants further study in a large controlled clinical trial.”

87. On August 6, 2015, Ohr issued a press release announcing its financial results for the third quarter of 2015. In the press release the Company discussed the IMPACT trial results, stating:

Patients with classic containing CNV demonstrated a mean gain in visual acuity at month nine of +11 letters for the OHR-102 combination arm and +5 letters with Lucentis® monotherapy, a clinically meaningful benefit of 6 letters.

Patients with an occult CNV area less than 10mm², regardless of classic CNV being present, treated with the combination of OHR-102 and Lucentis PRN, demonstrated a positive visual acuity benefit compared to the Lucentis monotherapy arm which was similar to that seen in the classic containing CNV population.

88. That same day, Ohr filed its financial report for the third quarter of 2015 with the SEC on Form 10-Q (“3Q 2015 10-Q”). The 3Q 2015 10-Q was signed by Taraporewala and

Backenroth and contained the same misleading statements as in the 2Q 2015 10-Q.

89. On December 10, 2015, Ohr issued a press release announcing the financial results for the fiscal year ended September 30, 2015. In the press release, the Company and Slakter stated:

In patients with classic CNV (ITT-LOCF), mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis® (anti-VEGF) monotherapy, a clinically meaningful benefit of +5.1 letters. . . .

Mean gains in visual acuity compared to baseline were +11.0 letters for the OHR-102 plus Lucentis combination arm and +5.7 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.3 letters in this occult <10mm² population.

90. In the press release, Defendant Slakter stated:

We successfully completed the Phase 2 IMPACT study in patients with wet AMD, demonstrating a positive and clinically meaningful treatment effect with OHR-102 combination therapy. The various analyses we conducted of the IMPACT data, which were featured at major ophthalmology meetings in the U.S. and internationally through the year, gave us insight into the mechanism of action of OHR-102 and identified the patients most likely to benefit from OHR-102 combination therapy. . . .

The strong body of clinical evidence we have accumulated supports our conviction that OHR-102 combination therapy has the potential to establish a new standard of care in wet AMD[.]

91. On February 9, 2016, Ohr filed its financial report for the first quarter of 2016 with the SEC on Form 10-Q ("1Q 2016 10-Q"). The 1Q 2016 10-Q was signed by Slakter and Backenroth and discussed the IMPACT trial results, stating:

In patients with classic CNV (ITT-LOCF), mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.1 letters. The positive effect on visual acuity in classic CNV was seen early in the course of treatment and continued to increase through the end of the study. . . .

In those patients with occult CNV less than 10mm² in area (n=94 of 128 completing study), 40% of those treated with OHR-102 combination therapy achieved a gain of 3 or more lines of vision, compared with 26% of patients in the Lucentis monotherapy arm, a 54% additional benefit. In addition, mean gains in

visual acuity compared to baseline were +11.0 letters for the OHR-102 combination arm and +5.7 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.3 letters. Importantly, this group of patients represents a larger proportion of the subjects enrolled in the IMPACT study than the classic containing group.

VII. Ohr Touts the MAKO Trial

92. On March 29, 2016, Ohr issued a press release, announcing an agreement on the Special Protocol Assessment with the FDA and that it had initiated the MAKO Trial, a phase III trial of Squalamine in patients with Wet AMD. The press release also was attached as exhibit 99.1 to the Form 8-K filed with the SEC that same day. In the press release, the Company stated:

NEW YORK, March 29, 2016 -- Ohr Pharmaceutical, Inc. (NASDAQ: OHRP), a clinical-stage biotechnology company developing novel therapies for ophthalmic diseases, today announced that it has reached an agreement on the Special Protocol Assessment (SPA) with the United States Food and Drug Administration (US FDA) on the design of the Phase III trial for its lead drug candidate, squalamine lactate ophthalmic solution, 0.2% ("Squalamine," also known as OHR-102). Based on the agreed upon SPA, Ohr has initiated the first of two planned Phase III global clinical studies evaluating the efficacy and safety of Squalamine, given in combination with Lucentis®, for the treatment of neovascular age-related macular degeneration (wet AMD).

"We are extremely pleased to have completed the SPA process. This agreement with the FDA enables us to move forward with the Squalamine Phase III clinical program," commented Dr. Jason Slakter, CEO of Ohr. "The initiation of our Phase III clinical program is a monumental achievement for the company and represents an important step in our mission to develop and commercialize therapeutics for unmet medical needs in ophthalmology."

"This is fantastic news for the retinal community and the patients in our care," said Dr. David S. Boyer, retina specialist at Retina-Vitreous Associates Medical Group, Beverly Hills, CA, and a member of Ohr's Scientific Advisory Board. "Based on my clinical experience, Squalamine is a promising drug with the potential to non-invasively improve visual function over the current standard of care. I look forward to the opportunity to enroll patients in this important clinical study."

Dr. Avner Ingerman, Ohr's Chief Clinical Officer, added, "We are working with the retinal community and Ohr's Scientific Advisory Board to expeditiously implement a high-quality Phase III clinical development program to fully support future regulatory applications."

The first of two randomized, double-masked, placebo-controlled trials will include approximately 165 centers in the United States and Canada and is expected to enroll approximately 650 treatment naïve subjects with wet AMD. The primary efficacy endpoint of the clinical trial is the change in visual function at nine months.

93. The MAKO Trial was designed to enroll 650 patients with occult CNV lesions of 10mm² or smaller. The trial was double-masked and patients would be randomly assigned to one of two arms: (1) in the Squalamine arm (i.e., the treatment arm) where patients would receive an initial dose of Lucentis and would thereafter self-administer Squalamine eye drops twice daily while also receiving monthly injections of Lucentis; and (2) in the Lucentis arm (i.e., the placebo control arm) where patients would receive an initial dose of Lucentis and would thereafter self-administer placebo eye drops twice daily while also receiving monthly injections of Lucentis.

94. Despite the announcement of the Mako Trial, Defendants did not stop issuing false and misleading statements concerning Squalamine.

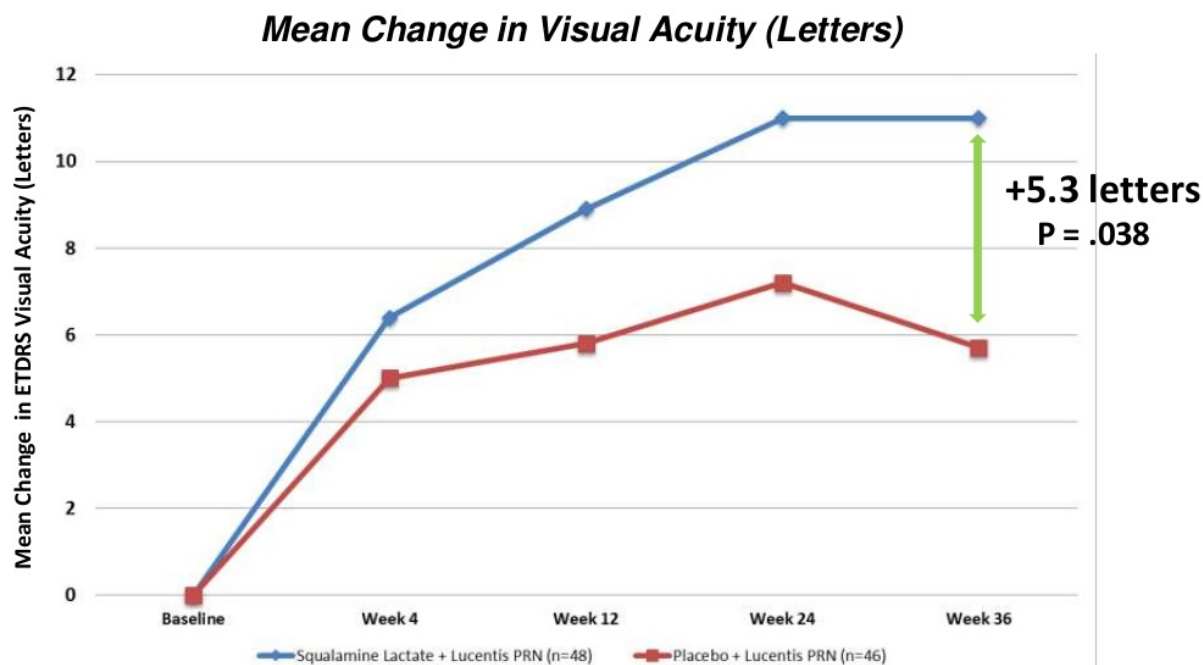
95. On May 10, 2016, Ohr filed its financial report for the second quarter of 2016 with the SEC on Form 10-Q ("2Q 2016 10-Q"). The 2Q 2016 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q.

96. On August 9, 2016, Ohr filed its financial report for the third quarter of 2016 with the SEC on Form 10-Q ("3Q 2016 10-Q"). The 3Q 2016 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q.

97. On October 13, 2016, Slakter presented at the Ophthalmology Innovation Summit hosted by American Academy of Ophthalmology. Slakter's presentation was accompanied by power point slides. The slides stated in relevant part concerning the Occult Lesions Results:

Positive Visual Outcomes in Occult CNV < 10mm²

Efficacy Consistent Through Month 9



Exploratory p-value

Squalamine Lactate Ophthalmic Solution Summary



- **Squalamine has the potential to be a convenient and cost-effective therapy in retinal disease**
- **Indication in Exudative AMD**
 - Unmet need for improved vision beyond anti-VEGF monotherapy
 - Strong phase 2 data supporting role of squalamine combination therapy in providing clinically meaningful vision gains
- **Use with Multiple Anti-VEGF Agents**
 - Combination effect with all current and future anti-VEGF agents
 - Topical delivery adaptable for use with any anti-VEGF treatment regimen/frequency
- **Multiple back-of-the-eye indications**
 - Initial data in investigator led clinical trial evaluating retinal vein occlusion indicate improved vision outcomes
 - Suggests potential role in retinal vascular disease (RVO and DME)

98. After announcing the MAKO Trial, as well as the “positive” results from the IMPACT Trial, on December 7, 2016, Defendants caused Ohr to launch another public offering in which the Company agreed to issue and sell 3,885,000 shares of common stock, together with Series A warrants to purchase up to 1,942,500 shares of common stock and Series B warrants to purchase up to 3,885,000 shares of common stock, for net proceeds of \$6.9 million.

99. On December 8 and 9, 2016, Ohr filed the prospectus supplement with the SEC on Form 424B5 for its offering. The prospectus supplement contained the same misleading statements as the 1Q 2016 10-Q.

100. On December 22, 2016, Ohr filed its annual report for the fiscal year ended September 30, 2016 with the SEC on Form 10-K (“2016 10-K”). The 2016 10-K was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q.

101. On February 14, 2017, Ohr filed its financial report for the first quarter of 2017 with the SEC on Form 10-Q (“1Q 2017 10-Q”). The 1Q 2017 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q.

102. On April 4 and 6, 2017, Ohr filed a prospectus supplement with the SEC on Form 424B5 for its offering of 20,250,032 shares of common stock, for total proceeds of approximately \$12.7 million. The prospectus supplement contained the same misleading statements as the 1Q 2016 10-Q.

103. On April 5, 2017, Ohr initiated its fourth offering of common stock in three years. Ohr agreed to sell 20,250,032 shares of common stock, together with warrants exercisable for up to 14,175,059 shares of common stock, for total proceeds of \$12.7 million. This offering of \$12.7 million, along with the offerings on April 8, 2014 (\$18 million), February 9, 2015 (\$25 million), and December 7, 2016 (\$6.9 million), resulted in total proceeds to Ohr of \$62 million.

104. On April 10, 2017, Ohr issued a press release, announcing that it plan to amend its clinical trial investigating Squalamine and that had funders through the end of 2018. The press release also was attached as exhibit 99.1 to the Form 8-K filed with the SEC that same day. In the press release, the Company stated:

NEW YORK, April XX, 2017 -- Ohr Pharmaceutical, Inc. (Nasdaq: OHRP), an ophthalmology research and development company, today announced that it plans to amend the ongoing clinical trial investigating Squalamine in wet-AMD (the MAKO Study) to enable efficacy analyses by the end of calendar 2017 or early 2018. The study remains a multi-center, randomized, double-masked, placebo controlled clinical trial. The subjects enrolled in the study, over 200 in total, will continue to receive their assigned study treatment of monthly Lucentis® and either Squalamine or placebo drops twice daily, and undergo scheduled visits and

assessments through nine months. The primary endpoint will be an assessment of visual acuity at nine months.

“This strategic approach should provide efficacy data by year end or early next year with the goal of confirming the benefits seen in the prior Phase 2 IMPACT study,” stated Dr. Jason Slakter, CEO. “The ongoing clinical trial has prospectively enrolled the patient population identified from the IMPACT study that has the greatest potential to benefit from Squalamine combination therapy. **We remain excited about the potential of Squalamine, a differentiated, topical, multi-target angiogenesis inhibitor, and believe that this is the optimal approach to help patients, maximize value for shareholders, and enhance our ongoing business development efforts.”**

Dr. Slakter continued, “Following the closing of the financing today, we are funded into 2018, including the completion of our ongoing clinical trial and data readout by the end of calendar 2017 or early 2018.”

105. On May 11, 2017, Ohr filed its financial report for the second quarter of 2017 with the SEC on Form 10-Q (“2Q 2017 10-Q”). The 2Q 2017 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q.

106. 110. On August 8, 2017, Ohr filed its financial report for the third quarter of 2017 with the SEC on Form 10-Q (“3Q 2017 10-Q”). The 3Q 2017 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q.

107. On December 15, 2017, Ohr filed its annual report for the fiscal year ended September 30, 2017 with the SEC on Form 10-K (“2017 10-K”). The 2017 10-K was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q.

108. Around this time, Ohr also launched a promotional campaign to bring additional attention to the MAKO Trial, presenting at investor conferences and industry meetings, giving phone interviews, and speaking with analysts.

109. On December 18, 2017, Kaiser inexplicably heightened his predictions to a **75 to 80% chance of success of the MAKO Trial**. See Yasmeen Rahimi, Company Note: OHRP: Docs

Are Bullish on the Success of MAKO Trial; Affirm Buy, Roth Capital Partners, 1-2 (Dec. 19, 2017). The stock rose 5% the following day.

110. During its presentations, Ohr continued to misrepresent the significance of the IMPACT Trial results and touted the likelihood of the MAKO trial's success. On July 12, 2017, Kaiser predicted a **60% chance of success of the MAKO Trial**. The stock rose 11% the following day.

111. The statements above were materially false and/or misleading because they misrepresented and failed to disclose the adverse facts pertaining to the Company's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose, inter alia, that:

- a) Genaera's prior clinical trials of Squalamine did not demonstrate that it improved visual acuity outcomes;
- b) Genaera terminated its development of Squalamine for the treatment of Wet AMD because Genaera concluded, based on the data available from its trials, that Squalamine was unlikely to produce vision improvement with the speed or frequency necessary to compete with Lucentis;
- c) The 6.3-letter mean visual acuity gain observed in the Lucentis Monotherapy Arm of the Interim Results underperformed the mean 7.94-letter-gain observed in prior studies of Lucentis;
- d) Had the Lucentis Monotherapy Arm of the Interim Results performed as well as in prior studies of Lucentis, the improvement of the Squalamine Arm compared to the Lucentis Monotherapy Arm would not have been clinically meaningful;
- e) The visual acuity gains observed in the Lucentis Monotherapy Arms of the Classic Lesions Results and the Occult Lesions Results underperformed prior Lucentis studies;
- f) Had the Lucentis Monotherapy Arms of the Classic Lesions Results and the Occult Lesions Results performed as well as in prior studies of Lucentis, the improvement of the Squalamine Arms compared to the Lucentis Monotherapy Arms would not have been clinically meaningful;
- g) As a result of the foregoing, Defendants' statements about Ohr's business, operations, and prospects, were false and misleading and/or lacked a reasonable basis; and

- h) The Company failed to maintain adequate disclosure controls and procedures with respect to its drug candidates, particularly Squalamine.

112. There is no doubt that Defendants knew or recklessly disregarded that the above statements were materially false and/or misleading.

113. Ohr and Defendants, as officers and directors of the Company, had possession of or access to information showing that the Squalamine trials conducted by Genaera were not successful because Glen Stoller, Ohr's CSO since May 2014, and Thomas Ciulla, a member of Ohr's Scientific Advisory Board from at least November 2013 to the end of 2015, both worked as investigators on Genaera's phase II trials.

114. In addition, when Ohr acquired the rights to Squalamine from Genaera, it also acquired the previous clinical trial data and Genaera's analyses and determinations regarding the data. Accordingly, Ohr and Defendants were in possession of and had access to the poor results from the Genaera trials showing that Squalamine did not improve patients' vision and were undoubtedly aware of Genaera's decision to abandon Squalamine.

115. Ohr and Defendants also were ly aware of the results from the prior Lucentis studies. For example, on the December 22, 2016 earnings conference call, Slakter stated:

When we first evaluated our phase 2 data, one of the first things we looked at was how closely our Lucentis monotherapy control arm performed compared to prior studies.

116. Moreover, many of Ohr's officers and advisors were involved in the prior Lucentis studies and would have known the outcomes of those studies and communicated the information to others as the Company:

Study	Year	Insiders
ANCHOR	2006	Kaiser, Brown, Heier ⁶

⁶ "Kaiser" refers to Peter K. Kaiser, M.D., Ohr's Head of Product Development from May 2014 to the present. "Heier" refers to Jeffrey S. Heier, M.D., an ophthalmologist based in Boston who

MARINA	2006	Kaiser, Brown, Boyer Heier
VIEW1 and VIEW2	2012	Kaiser, Brown, Heier
HARBOR	2013	Brown, Heier
VIEW 96-Week Follow Up	2013	Kaiser, Brown, Slakter, Heier

117. Furthermore, Squalamine is the primary product of the Company. As such, Defendants, as directors and officers, would have certainly been aware of the true facts surrounding it and the statements being made publicly concerning it.

VIII. The Truth Emerges

118. After the market closed on January 4, 2018, Ohr issued a press release, announcing the efficacy results from the MAKO Trial. Ohr announced that the Phase III MAKO Trial did not meet its primary efficacy endpoint of mean visual acuity. In fact, patients receiving Squalamine eye drops performed worse than patients receiving placebo eye drops. The press release also was attached as exhibit 99.1 to the Form 8-K filed with the SEC the following day. In the press release, the Company stated:

Ohr Pharmaceutical Announces Efficacy Results from the MAKO Study in Wet-AMD

NEW YORK, New York – January 5, 2018 – Ohr Pharmaceutical, Inc. (NASDAQ: OHRP), a clinical-stage pharmaceutical company developing novel therapies for ophthalmic diseases, today reported topline data from the MAKO study which did not meet its primary efficacy endpoint. The MAKO study evaluated the efficacy and safety of topically administered squalamine in combination with monthly Lucentis® injections for the treatment of wet age-related macular degeneration (“wet-AMD”). The primary efficacy endpoint was the mean visual acuity gain at nine months, using a mixed-effects model for repeated measures (MMRM) analysis. **Subjects receiving squalamine combination therapy (n=119) achieved a mean gain of 8.33 letters from baseline versus**

has served as a member of Ohr’s Scientific Advisory Board since at least November 2013. “Boyer” refers to David S. Boyer, M.D., an ophthalmologist based in Los Angeles who has served as a member of Ohr’s Scientific Advisory Board since at least November 2013.

10.58 letters from baseline with Lucentis® monotherapy (n=118). There were no differences in the safety profile between the two treatment groups.

“We are very disappointed with the outcome of the MAKO study,” commented Dr. Jason Slakter, chief executive officer of Ohr. “We are grateful to the patients and physicians who participated in the clinical trial. Based on these results, we intend to evaluate strategic alternatives to maximize shareholder value.”

119. On this news, the Company’s common stock price declined \$1.64, or approximately 81%, from \$2.02 per share on January 4, 2018, to \$0.38 per share on January 5, 2018.

DAMAGES TO OHR

120. As a result of Defendants improprieties, Ohr disseminated improper, public statements concerning Squalamine and its impact on the Company’s business, operations, and prospects. Ohr is now the subject of a securities class action lawsuit as a result. These improper statements also devastated the Company’s credibility and future prospects as evidenced by the collapse of the Company’s stock price by approximately 81% following the disclosure of the truth.

121. In addition, as a direct and proximate result of Defendants’ actions, Ohr has expended, and will continue to expend, significant sums of money. Such expenses include, but are not limited to:

- a) costs and damages incurred from defending and paying any settlement or judgment in the Securities Class Action for violation;
- b) costs incurred to investigate the wrongdoing internally; and
- c) costs incurred from compensation and benefits paid to Defendants who breached their fiduciary duties to the Company.

DEMAND FUTILITY

122. Plaintiff brings this action derivatively on behalf of Ohr to redress injuries suffered, and to be suffered, by the Company as a direct and proximate result of Defendants' misconduct, breach of fiduciary duties, corporate waste and unjust enrichment.

123. Plaintiff owns, and has owned, Ohr stock continuously during the time of the wrongful course of conduct.

124. Plaintiff will adequately and fairly represent the interests of Ohr in enforcing and prosecuting its rights and has retained counsel competent and experienced in stockholder derivative litigation.

125. Plaintiff did not make a demand on the Board prior to instituting this stockholder derivative litigation because a pre-suit demand upon the Board would be futile. At the time of this filing, the Board consists of the following five (5) directors: Ferguson, Slakter, Hirschman, Riedhammer and Almenoff. Demand is excused because a majority of the Board are neither independent nor disinterested.

Demand is Excused Because Defendants Ferguson, Slakter, Hirschman, Riedhammer and Almenoff Face a Substantial Likelihood Liability for Their Misconduct

126. Defendants Ferguson, Slakter, Hirschman, Riedhammer and Almenoff were responsible for overseeing the Company's public statements concerning its products, including Squalamine, and the Company's public statements concerning its business practices and operations. Defendants authorized, or failed to prevent, false statements concerning Squalamine and the Company's business, operations, and prospects made during the Relevant Period. Accordingly, Defendants Ferguson, Slakter, Hirschman, Riedhammer and Almenoff were active participants in breaches of good faith, candor, and loyalty, and have subjected the Company to a class action lawsuit claiming violations of the federal securities laws. Because Ferguson, Slakter, Hirschman, Riedhammer and Almenoff caused and/or allowed the Company to engaged in the

unlawful conducted alleged here, these defendants face a substantial likelihood of liability. As a result, any demand upon defendants Ferguson, Slakter, Hirschman, Riedhammer and Almenoff to bring suit against themselves would be futile.

127. As members of the Audit Committee, Defendants Hirschman, Riedhammer, and Almenoff were tasked with reviewing and overseeing issuance of the improper statements. The Audit Committee's Charter provides that it is responsible for oversee the Company's accounting and financial reporting policies and practices, as well as discussing and reviewing press releases prior to their release. Thus, Defendants Hirschman, Riedhammer, and Almenoff were responsible for knowingly or recklessly allowing the improper statements related to including Squalamine and the Company's business practices and operations. Accordingly, Hirschman, Riedhammer, and Almenoff breached their fiduciary duties of loyalty and good faith because they participated in the wrongdoing describer here, and face a substantial likelihood of liability for having done so, making demand futile.

128. As CEO, Defendant Slakter was subject to the Purpose of Code of Ethics. The Code provides that the Company's executives were required to comply with both the letter and spirit of all applicable governmental rules and regulations, including federal securities laws. Thus, Defendant Slakter knowingly or recklessly made, or allowed to be made, the improper statements related to including Squalamine and the Company's business practices and operations. Accordingly, Defendant Slakter breached his fiduciary duties of loyalty and good faith because he participated in the wrongdoing describer here, and faces a substantial likelihood of liability for having done so, making demand futile.

Demand is Excused as to Defendant Slakter Because He Lacks Independence

129. Defendant Slakter is incapable of independently considering a demand because he is Ohr's CEO and as such derives the majority of his income from the Company. In 2015 and 2016, Slakter received \$610,622 and \$1,958,813 from the Company. Accordingly, Defendant Slakter lacks independence from Defendants Ferguson, Hirschman, Riedhammer and Almenoff due to his interest in maintaining his executive position at Ohr. The lack of independence renders Defendant Slakter incapable of impartially considering a demand to commence and vigorously prosecute this action.

130. The Company has confirmed that Defendant Slakter is not independent. In the Company's most recent Schedule 14A Proxy Statement, filed with the SEC on April 14, 2017, the Company disclosed that Slakter is not independent under the NASDAQ rules.

CAUSES OF ACTION

COUNT I BREACH OF FIDUCIARY DUTIES (derivatively against All Defendants)

131. Plaintiff repeats and re-alleges each and every allegation above as if set forth fully herein.

132. By their wrongful acts and omissions, defendants breached their fiduciary duties of candor, good faith, and loyalty. Specifically, Defendants breached their fiduciary duties by consciously performing or failing to prevent the Company from engaging in the unlawful acts complained of herein.

133. Defendants breached their fiduciary duties by recklessly permitting the improper statements identified herein, rendering them liable to the Company for breaching their duties. Defendants knew or were reckless in not knowing that: (1) caused or allowed Ohr to disseminate improper statements concerning Ohr's lead product Squalamine; (2) caused or allowed Ohr to

disseminate improper statements concerning its business, operations, and prospects; and (3) failed to maintain adequate internal controls and disclosure procedures with respect to Ohr's drug candidates.

134. Defendant Slakter either knew, was reckless, or was grossly negligence in disregarding the unlawful acts complained of herein. Defendant Slakter either knew, was reckless, or was grossly negligent in not knowing that: (1) caused or allowed Ohr to disseminate improper statements concerning Ohr's lead product Squalamine; (2) caused or allowed Ohr to disseminate improper statements concerning its business, operations, and prospects; and (3) failed to maintain adequate internal controls and disclosure procedures with respect to Ohr's drug candidates.

135. As a direct and proximate result of Defendants breaches of their fiduciary obligations, the Company has been harmed.

136. The Company has no adequate remedy at law.

COUNT II
WASTE OF CORPORATE ASSETS
(derivatively against Defendants)

137. Plaintiff repeats and re-alleges each and every allegation above as if set forth fully herein.

138. Defendants breached their fiduciary duties by failing to properly supervise and monitor the adequacy of Ohr's disclosure controls and procedures, by issuing, causing the issuance of, and/or failing to correct the false and misleading statements identified herein, and by allowing the Company to engage in this improper code of conduct, which was continuous, connected, and ongoing throughout the relevant period. It resulted in continuous, connect, and ongoing harm to the Company.

139. As a result of the misconduct described above, Defendants have caused Ohr to waste its assets by paying improper compensation and bonuses to certain of its executive officers

and directors that breached their fiduciary duty; and incurring potentially millions of dollars of legal liability and/or legal costs to defend Defendants' unlawful actions, including defendant the Company and its officers against the securities class action lawsuit.

140. As a direct and proximate result of these Defendants' breaches of fiduciary duties, the Company has suffered significant damages, as alleged herein. As a result of the waste of corporate assets, Defendants are liable to the Company.

141. The Company has no adequate remedy at law.

COUNT III
UNJUST ENRICHMENT
(derivatively against Defendants)

142. Plaintiff repeats and re-alleges each and every allegation above as if set forth fully herein.

143. By their wrongful acts and omissions, Defendants were unjustly enriched at the expense of, and to the detriment of, Ohr. Defendants were unjustly enriched as a result of the compensation and director remuneration they received while breaching fiduciary duties owed to Ohr.

144. Plaintiff, as a stockholder and representative of Ohr, seeks restitution from these defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

145. The Company has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

A. A judgment against all Defendants for the amount of damages sustained by the Company as a result of the Defendants' wrongdoing as alleged herein;

B. Directing OHR to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect OHR and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the Company's By-Laws or Articles of Incorporation, and taking such other action as may be necessary to place before shareholders for a vote the following corporate governance proposals or policies:

- a. a proposal to strengthen Ohr's oversight of its disclosure procedures
- b. a proposal to strengthen the Company's controls over financial reporting;
- c. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board; and
- d. a proposal to merit the shareholders of Ohr to nominate at least two candidates for election to the Board.

C. Extraordinary equitable and/or injunctive relief as permitted by law, equity and the state statutory provisions sued hereunder, including attaching, impounding, and imposing a constructive trust on or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that plaintiff on behalf of Ohr has an effective remedy;

D. Awarding to Ohr restitution from Defendants, and each of them, including ordering disgorgement of all profits, benefits and other compensation obtained by defendants;

E. Awarding Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs and expenses; and

F. A grant of such other, further relief, whether similar or different, including damages, as this Court may deem just and proper.

Dated: September 6, 2018
New York, NY

LEVI & KORSINSKY, LLP

/s/ Joseph Levi

Joseph Levi

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